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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,819	12/21/2001	Colleen E. Hayes	032026-0700	6475

23524 7590 04/22/2004

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,819	HAYES ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 21-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 21-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,6,7</u> . | 6) <input type="checkbox"/> Other: _____ |

OFFICE ACTION ON MERITS

1. Acknowledgement is made of the response file in paper no. 9. Amendments are entered. Claims 21-44 are pending. No claim is allowed at present time.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The arguments filed by applicants were fully considered but are found persuasive in-part therefore the double patenting rejection is withdrawn, the arguments regarding rejection under 103 (a) are not found persuasive therefore rejection is maintained. Even though method of treating IBD for specific vitamin D compound as presently claimed is not taught by the reference, the reference teaches the use of active biologically active vitamin D compounds for the treatment of IBD. The term comprising used in claims allows other ingredients to be added.
4. Claims 21-44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Snowden (US Patent 6,214,373). The reference teaches a nutritional composition of vitamin D and method for treating inflammatory bowel disease such as Crohn's disease or ulcerative colitis, which embraces instantly, claimed invention. See the entire document especially lines 59-65, col. 1; lines 27-59, col. 2; lines 9-54, col. 4; lines 1-30, col. 5; Tables 1 and 2 and claims.
5. Instant claims differ from the reference in claiming the method of use of specific vitamin D compounds, vitamin D2 and 19-nor vitamin D3 whereas prior art teaches any vitamin D compound. Example of the instant invention and prior art teach 1alpha, 25 hydroxy vitamin D3.

Claim Rejections - 35 USC § 103

6. Claims 21-44 rejected under 35 U.S.C. 103(a) as being unpatentable over Neef et al. US Patent 5,446,035. See the entire document especially lines 34 and 35 in col. 6; lines 15-31.
7. Instant claims differ from the reference in claiming few specific compounds for the treatment of inflammatory bowel diseases wherein prior art teaches a broader range of vitamin D

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compounds which are potent vitamin D receptor antagonists, and may be useful for inflammatory disorders like arthritis, colitis ulcerosa and ileitis terminalis.

8. It would have obvious to one skilled in the art at the time of invention to prepare vitamin D derivatives for use as anti-inflammatory agent for the treatment of inflammatory bowel disease as presently claimed. There is a motivation provided by the prior art that these compounds may be useful for the treatment of colitis ulcerosa. The expectation is due to the teaching of the prior art that these compounds are potent vitamin D receptor antagonists.

In absence of any showing of unexpected and/or unobvious results, presently claimed invention is considered obvious over the prior art.


9. In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Sabiha N. Qazi
Primary Examiner
Art Unit 1616
